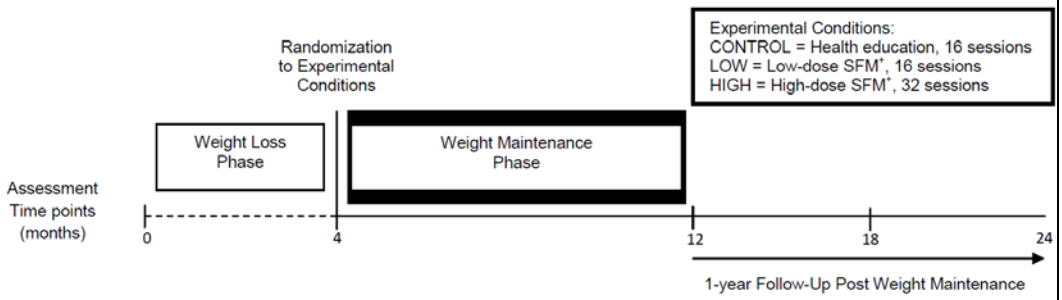
D. RESEARCH DESIGN AND METHODS

D.1. Overview of Study Design

We propose a three-group, controlled, comparative maintenance design to evaluate the optimal dose and content of a comprehensive socio-environmental treatment to improve the long-term maintenance of child weight loss. The proposed study will examine whether the content and/or number of sessions of weight maintenance treatment is important for improving long-term maintenance. The duration of treatment will be controlled across all conditions (8 months) while the content (health education vs. SFM+) and the number of sessions in SFM+ will vary (LOW = 16 sessions vs. HIGH = 32 sessions). This efficient study design enables us to simultaneously examine the impact of content and dose, two critical aspects of weight loss maintenance interventions that need to be addressed if we are to reduce the rates of CO and its associated health consequences. Children, along with at least one parent, will complete a four-month FBT program. Participants will then be stratified by age, race, sex, level of social problems, and change in percent overweight, and randomly assigned to one of three maintenance conditions: 1) low dose SFM+ (LOW), 2) high dose SFM+ (HIGH), or 3) weight-management education intervention (CONTROL) **(see Figure 1)**. The design includes the main factor of Group (LOW, HIGH, CONTROL), and a repeated factor of Time (0, 4, 12, 18, and 24 months). The CONTROL and LOW groups will be matched for number of treatment sessions, to permit examination of the content efficacy of SFM+ while controlling for interventionist contact and treatment duration. The LOW and HIGH groups will both receive SFM+ treatment materials over the same duration but will vary on number of sessions (16 vs. 32) to examine the impact of dose on outcome.

Figure 1: Overview of Study Design



The study will be conducted at two clinical sites. Data management, as well as quality control of assessment and treatment procedures, will be conducted by a Data Coordinating Center (DCC). The PI, a Study Executive Committee (SEC), and an independent Data Safety and Monitoring Board (DSMB) will provide study oversight.

D.2. Participants

Participants will include 240 children with overweight or obesity, aged 7-11, and their parents. In order to target children most at-risk for remaining overweight as adults,[1] at least one of the parents must have a BMI ≥ 25 kg/m^2. Given the high rates of adult overweight, this restriction will not likely exclude many families. The weight criterion for children is a BMI that is at or above the 85th percentile for their sex and age.

Family Participation

The participating child and at least one parent must agree to attend all treatment meetings. For families in which only one parent is overweight, that parent will be encouraged to participate. If both parents are overweight, the family will choose one as the identified participating parent. Though only the overweight child and the participating parent will be required to attend treatment sessions, all family members living in the household (i.e., both parents and all siblings), will be encouraged to support changes in the family's lifestyle. Prior to treatment, the participating child and parent will consent to participate in both intervention components of the study. Families will be aware from the outset that they will be randomly assigned to a maintenance condition and that they will not learn the

specific maintenance condition to which they have been assigned until the end of the weight loss phase.

Exclusion Criteria

Families will be excluded if there is: a) a thought disorder, suicidal ideation, bipolar disorder, or drug or alcohol dependence in either the participating parent or the participating child; b) an inability of the child or participating parent to comprehend English at a 1st-grade level; c) a physical disability or illness in either the participating parent or the child that precludes physical activity at a level equivalent to a brisk walk or requires severe dietary restriction; d) a medication regimen for either the child or the participating parent that affects his or her weight. In addition, since parental eating disturbance has been linked to an increased risk of child eating disturbances,[2-4] parents (participating and nonparticipating) and children will be excluded if they are diagnosed with an eating disorder (i.e., anorexia nervosa, bulimia nervosa, binge eating disorder) or have sub-clinical levels of eating disturbance (i.e., reporting key eating disorder behaviors of purging, fasting, or binge eating more than two times per month).[5] The various problems detailed in the exclusion criteria may interfere with treatment implementation, and families with these problems could add variability to treatment effects, thus decreasing the statistical power of this efficacy study.

General Recruitment

Both Drs. Wilfley and Saelens have successfully recruited participants for several clinical trials. St. Louis and Seattle are ideal locations for recruitment as they are both large metropolitan areas (i.e., both cities are among the top 20 most populous metropolitan regions in the United States). Further, Dr. Wilfley has an established history of recruiting for other studies in St. Louis, and has successfully used the Washington University Pediatric and Adolescent Ambulatory Research Consortium (WUPAARC), an established practice-based research network of 68 community pediatricians affiliated with Washington University Medical School (WUSM) with over 100,000 children and adolescents in their practices. Dr. Saelens has the support of the director of the Center for Health Services and Behavioral Sciences and the Children's Obesity Action Team (COAT) at Seattle Children's Hospital and Regional Medical Center, which recently established a Child Wellness Clinic targeting childhood overweight. At both sites, participants will be recruited through local media outlets (television, newspaper, Internet, and radio), schools and organizations, physician referrals from pediatrician offices, and clinics treating weight problems and obesity. Given previous success with these and other recruitment strategies we do not anticipate any problems recruiting the targeted sample size at each site.

A separate consent form will be used for saliva sample collection, as not to interfere with recruitment of participants to the study. Participants who choose not to sign the consent form for saliva collection will still be eligible for the proposed study. Upon consent, participants will be asked to spit into a non-invasive collection tube to collect a saliva sample, which will be stored for future analyses and will be labeled with a study ID number. Potential donors will be apprised of this in the consent form and also informed that their name or other public identifiers will not be included with any data shared with other investigators, or in any published materials. The child or parent may withdraw his or her consent for use of the sample at any time.

Families will also have the option of signing an additional consent form to allow Dr. Wilfley and the study team to contact their pediatrician or primary care physician.

Recruitment of Both Genders. Prevalence rates for overweight are similar for male and female children (18.2% and 16.0%, respectively)[6] and we plan to recruit equal numbers of male and female children.

Recruitment of Ethnically Diverse Participants. As obesity is a significant problem among racially/ethnically diverse populations,[7,8] we will make strong efforts to obtain an ethnically representative sample. We have an established history of recruiting diverse samples in previous research, including in our previously completed study (7.3% Black, 18.7% Hispanic, 3.3% Other or multiple race/ethnicity). Each recruitment site for the proposed study is ethnically diverse: the ethnic

breakdown of the St. Louis area is 75% Caucasian, 22% African-American, and less than 3% Asian, Hispanic, Native American and Pacific Islander combined. Based on the 2005 American Community Survey update of the U.S. Census population estimates of race, the greater Seattle metropolitan area (King County, WA) is 73.1% Caucasian/white, 13.3% Asian, 5.7% Black or African-American, and about 7.9% other races and individuals of multiple races.

We will use a community outreach approach focusing on forming liaisons with leaders of community-based multi-cultural organizations (e.g., African-American neighborhood associations). These liaisons are community leaders who are familiar with and committed to the wellbeing of their community. They work to bridge the gap of language, knowledge, and values between cultures via familiarizing their communities with our available services through word-of-mouth referrals, community assessment, and education. We have colleagues with links to, and established liaisons in, the ethnically diverse communities within our geographic areas. We will also encourage these liaisons to provide information and materials (e.g., study brochures) to community clinics and offer recommendations for media outlets targeted specifically for these populations. The proposed study also provides a culturally sensitive treatment approach. The study's focus on the family rather than on the individual as the unit of treatment is consistent with collectivistic, ethnically diverse populations.

D.3. Description of the Weight Loss and Maintenance Treatments

Family-based Behavioral Treatment (FBT)

In the present study, FBT treatment sessions are held weekly for 4 months for a total of 16 sessions **(see Table 1)**. FBT is an extensively studied and validated intervention that has been associated with beneficial changes in child percent overweight.[9,10] The treatment includes: 1) diet (reducing caloric intake and improving dietary quality as outlined in the *Traffic Light Diet*);[11] 2) physical activity (a maximum goal of 90 minutes per day for children and 60 minutes per day for parents on at least 5 days per week); and 3) behavior change. FBT is a mixed treatment of individual family meetings and separate parent-only/child-only groups. During each treatment meeting, parents and children are first weighed and have a 30-minute individual family meeting with a family interventionist, during which time the family's diet/activity self-monitoring are reviewed and any barriers to adherence with the weight-loss behaviors are addressed. After this family session, the child and parent go to their respective 45-minute group meetings. All families receive similar information for: 1) diet; 2) behavioral and parenting principles; 3) the importance of physical activity and reducing sedentary behavior; 4) the potential negative effects of sedentary behavior on physical activity and eating patterns; and 5) the interference of sedentary behaviors with other activities such as schoolwork. In general, the content of the group sessions is similar for parents and children, although tailored for the developmental level of the participants. Several behavior change techniques are taught: 1) self-monitoring, 2) positive reinforcement through praise and reciprocal contracting, 3) stimulus control, and 4) modeling.

Table 1: Treatment Schedule for FBT and Maintenance Conditions

			Week														
Weight Loss Condition	*Maintenance Condition*	*Sessions*	2	4	6	8	10	12	14	16	18	20	22	24	26	28	30	32
FBT (16 sessions in 16 weeks)	CONTROL	16	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	LOW	16	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
	HIGH	32	X X	X X	X X	X X	X X	X X	X X	X X	X X	X X	X X	X X	X X	X X	X X	X X
Lesson number:			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

Schedule of Contacts and Structure of Maintenance Groups

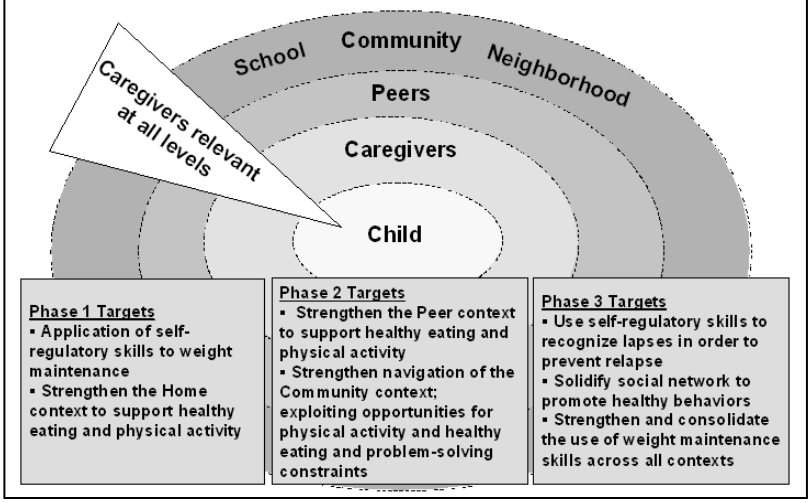
All maintenance conditions (CONTROL, LOW, and HIGH) are delivered over a 32-week period of time following the end of FBT **(see Table 1)**. The interactive group format consists of homework reports from the previous session when applicable, didactic presentation on the current topic, discussion of the topic with interactive exercises, and new homework assignments. Although all conditions share this group format, the SFM+ conditions differ in dose. The schedule of treatment

contacts for the CONTROL and the LOW conditions is 16 contacts delivered over 32 weeks, while it is doubled for the HIGH condition: 32 contacts over 32 weeks. Although the content presented is the same for participants in both the LOW and the HIGH conditions, doubling the number of contacts in the HIGH group allows for more in-depth discussion and practice of key skills and concepts. For example, if the lesson content for a particular week is being teased by peers for healthy food choices, the participants in both the LOW and the HIGH condition will be taught skills to navigate this type of high-risk situation and be given homework designed to encourage actively practicing these skills in a context outside of the treatment setting. However, given their higher frequency of treatment contact, the participants in the HIGH condition will receive feedback and reinforcement more often from fellow group members, family interventionists, and group leaders for practicing their new behaviors than the participants in the LOW condition and will have an additional opportunity to integrate this feedback into their next attempt to use these newly acquired skills in yet another context. Thus, the repeated, novel exposures to maintenance skills should facilitate the consolidation and mastery of new learning for HIGH dose participants.

Enhanced Social Facilitation Maintenance Treatment (SFM+)

SFM+ is designed to optimize the durability of changes in eating and physical activity behaviors through the application of self-regulatory skills and learning theory principles to the practice of weight maintenance behaviors across multiple socio-environmental contexts. This multi-level approach to behavior change targets the many contexts in which behavior occurs by strengthening home and peer support for persistence in the use of weight maintenance skills **(see Figure 2)**. The goals of SFM+ are to: 1) maintain weight at no more than three pounds above end of FBT weight, 2) adhere to an individualized caloric level consistent with weight maintenance (usually 1500-1800 calories/day), and 3) increase frequency, duration, and intensity of physical activity to a level (usually 60-90 minutes/day) that will achieve energy balance with the increased maintenance caloric intake.

Figure 2. Enhanced Social Facilitation Maintenance Treatment (SFM+): A Social-Environmental Model



SFM+ retains the mixed treatment format begun in FBT. This format allows individual family interventionists to use the 30 minutes prior to or after the group meetings to review individualized goals with each family, to praise successes, and to discuss any implementation problems in meeting treatment goals. The 45-minute concurrent parent and child group sessions are interactive and provide developmentally tailored, similar information to both groups. The group interventions and recommended activities are designed to target weight maintenance and to identify barriers to making and maintaining positive changes across contexts. The group interventions also offer both parents and children an avenue for the peer support encouraged in SFM+ in addition to working on changing their home and peer environments. Concepts are revisited throughout treatment, enhancing the opportunity for mastery across multiple, relevant contexts. Thus, SFM+ builds behavioral momentum from phase to phase.

Phase 1--Applying self-regulatory skills to weight maintenance and strengthening the shared home environment*:* Phase 1 focuses on applying behavioral skills initially introduced in FBT to the new goal of weight maintenance. Key tasks include the use of self-regulatory skills such as self-monitoring of weight and weight maintenance behaviors via abbreviated tracking forms. If weight goes above the maintenance range, participants are instructed to temporarily return to weight-loss

self-monitoring tools and behaviors (e.g., detailed food and physical activity recordings and the lower 1200-1500 caloric range). Families are taught to use weight gain as a signal for the need to assess their home, peer, and/or community environments and to problem-solve how best to support weight maintenance behaviors. In this first phase, particular attention is paid to the examination of the home context. Parents and children are instructed to assess the home for its conduciveness to weight maintenance versus weight regain (e.g., the availability of cues for eating high-calorie foods such as bowls of candy versus the availability of healthy snacks). Parents are encouraged to model healthy lifestyle behaviors and to improve general family functioning, such as family cohesion, mutual support, communication skills, and discipline in order to increase instrumental support for their child's weight maintenance behaviors. Potential problem areas are evaluated and addressed, including the quality of family meal times and access to opportunities for increased physical activity.

Phase 2--Strengthening peer and community support for weight maintenance behaviors*:* As participants continue to use the skills acquired in Phase 1, the focus in Phase 2 shifts to strengthening the peer and community contexts in order to further support healthy eating and physical activity. Evaluations of the child's current social skills and peer environment are used to inform treatment. Self-monitoring and goal-setting targets include the frequency and quality of peer interactions related to healthy eating and time spent in physically active rather than sedentary interactions with peers. Parents are taught developmentally appropriate ways to facilitate their child's efforts to establish a supportive social environment for weight maintenance behaviors. Once an appropriate, supportive peer group (possibly modifying an existing one) is established, parents and children are encouraged to identify and engage in active social activities (e.g., at parks or pools) rather than those involving food and sedentary behaviors. As appropriate, parents and children are taught to identify and alter cognitive and social barriers to ongoing weight maintenance efforts such as negative body image and teasing. Within the school environment, families will assess potential barriers to ongoing healthy eating and activity (e.g., unhealthy food choices in the cafeteria) as well as opportunities for the practice of weight maintenance behaviors (e.g., extra-curricular activities). Using innovative web-based mapping tools, the treatment team will assist families to assess neighborhood resources that are supportive of healthy lifestyle behaviors (such as parks and recreational sports) and to develop plans to increase utilization of these resources in support of their weight maintenance efforts (e.g., to increase walking or biking rather than driving for errands in close proximity to the home based upon identification of safe routes).

Phase 3--Strengthening and consolidating weight maintenance across relevant contexts: Throughout SFM+, attention is paid to integrating skills learned during each preceding phase. In this way, participants can transfer newly acquired weight maintenance skills between contexts and across time, thus increasing the durability of behavior change.[12] In this final phase of SFM+, parents are encouraged to continue leading the family in practicing healthy behaviors. Participants are encouraged to practice skills for dealing with high-risk social and environmental situations and contexts (e.g., disruptions in family schedules, school parties). In this way, parents and children can better recognize "lapses" (as signaled by weight gain) in a range of new contexts and get back on track with healthy eating and physical activity goals in order to prevent relapse. Principles from learning theory are applied often in this last phase of treatment. When possible, participants develop and place retrieval cues (e.g., sports equipment or self-monitoring materials) in multiple locations to prompt the use of weight maintenance skills. In addition, families learn to recognize different contexts (e.g., certain fast food restaurants) related to their original, unhealthy behaviors and to avoid these contexts. Alternatively, participants learn to bring cues or prompts for weight maintenance such as a note card with suggested healthier food choices written on it, into high-risk contexts. Participants develop lists of community resources and events supportive of weight maintenance behaviors (including those identified in earlier phases), and make plans to increase utilization of these resources. Finally, as treatment comes to an end, families develop detailed and individualized plans for the continued use of weight maintenance skills learned in SFM+. Parents and children use these

plans as cues or prompts for the continued use of weight maintenance skills following the end of treatment.

Weight-management Education Intervention (CONTROL)

The purpose of the CONTROL condition is to control for staff attention and for contextual components of the treatment setting. In choosing to use a health education control, we were guided by two objectives: (1) to maximize participant retention and (2) to utilize an intervention that participants perceive as beneficial. The CONTROL condition includes a series of interactive workshops focused on important general information about healthy eating and physical activity of interest to children and their parents. Parents and children meet for 75 minutes in concurrent groups. The groups receive similar health topics, tailored to the developmental level of the participants. Although the health education parent and child groups receive ongoing staff attention, the weight of participants randomized to the CONTROL condition is **not** monitored on an ongoing basis by the clinical site staff, except as part of the assessments at weeks 8, 16, 24, and 32 of the maintenance treatment. If a participant expresses concerns regarding weight regain, the clinical site staff, in a general way, will encourage the participant to return to the use of the skills learned during FBT. However, clinical site staff will **not** provide specific coaching or feedback in the use of behavioral self-regulation strategies, nor will they provide training in relapse prevention skills or other treatment-specific content that are part of SFM+. Since these treatment components are purposely omitted from the CONTROL condition, the individual family meeting format is also omitted. Although SFM+ and CONTROL are not matched for format, they are matched for staff contact and treatment context (where the original weight loss skills were taught). The extended contact with treatment staff, along with brief reminders from treatment staff to return to the skills and materials from FBT, may be sufficient to prompt weight maintenance for some CONTROL participants. In addition, if just the continued treatment contact, rather than the specific weight maintenance content, is the active ingredient in extended care approaches, then the CONTROL condition may have the advantage of providing the families with novel content, thus preventing attendance "burn-out." This adherence to scheduled treatment contacts may then result in weight maintenance for the duration of participation in this condition.

Allocation of Interventionists to Treatment

Each family will be assigned an individual family interventionist upon entering FBT, and again upon randomization. The parent group sessions will be led by one of the Ph.D.- or M.A.-level interventionists, and the child group sessions will be led by M.A.- or B.A.-level interventionists.

Interventionist Training and Treatment Fidelity

Initial training of the interventionists will coincide with the first meeting of the Study Executive Committee (SEC) at Washington University. Training will include a workshop on the three treatments [FBT (co-leaders Drs. Wilfley and Epstein), and HIGH and LOW SFM+ (Drs. Wilfley and Saelens). Before these workshops, interventionists will engage in detailed review of the treatment manuals. Prior to administering treatment, interventionists will review audiotapes, videotapes, or live observations of each treatment conducted in accordance with the treatment manuals. Each interventionist will then audiotape his/her treatment sessions, which will be reviewed in weekly supervision meetings by M.A.- and Ph.D.-level supervisors. If an interventionist's approach is not in accordance with the treatment manuals, he or she will be given specific feedback and recommendations to achieve protocol adherence. In years 1-2, there will be 2 annual training/calibration workshops coinciding with the SEC meetings. In addition, throughout the treatment phase of the study, weekly onsite supervision meetings will be held, and bi-weekly cross-site supervision calls will be scheduled to assist with standardization of protocols across the two treatment centers. Drs. Epstein and Perri will be available for consultation during these cross-site supervision calls; they will serve as expert resources for any questions regarding the treatment protocols.

Treatment Integrity

The goal of treatment integrity assessment is to measure the delivery of FBT, the CONTROL, and the HIGH and LOW SFM+ maintenance treatment sessions, to ensure protocol adherence, and to certify that non-treatment components and cross-treatment contamination are minimized.[13] Various supervisors will listen to audio recordings of treatment sessions and give feedback.

Additional Treatment Seeking

A semi-structured interview will be administered at each time point to assess parents' and children's other weight loss and psychiatric treatment seeking as well as any significant child or parent health changes.

D.4. Assessment

Overview

There will be 5 major assessment points (0 months, 4 months, post-weight maintenance [12 months], 18 month follow-up, and 1-year follow-up [24 months]). Four brief assessments at weeks 8, 16, 24, and 32 of the maintenance treatment will be conducted to assess hypothesized mediators of treatment response**.** Assessor training will coincide with interventionist training sessions (2 times per year in years 1-2) and with one SEC meeting in year 3.

Treatment Outcome

The primary outcome variable is change in child percent overweight. We will calculate change in z-BMI and BMI to verify that the pattern remains the same with these alternate metrics of relative weight status. These variables will be calculated from each child's height and weight, which will be measured at each assessment point and at weeks 8, 16, 24, and 32 during maintenance treatment. Secondary outcome variables comprise four additional domains: body composition and health-related variables (e.g., fat and lean body mass), energy-balance behaviors (e.g., dietary intake, physical activity); psychosocial functioning (e.g., psychological functioning, quality of life); and socio-environmental influences on eating and physical activity (e.g., home environment, peer support). These will be measured at each major assessment point.

Moderator and Predictor Variables

Moderators in RCTs are baseline variables that specify for whom and under what conditions treatment works, allowing division into subgroups more or less likely to respond to treatment, and that provide valuable information for dissemination and/or future studies.[14] We have one a priori moderator. Based on our previous study, we hypothesize that baseline level of child social problems prior to maintenance treatment will moderate maintenance treatment effects (e.g., children with high social problems will have better maintenance of weight loss in the HIGH dose group than children with high social problems in the LOW and CONTROL groups). On an exploratory basis, we propose to examine a number of additional variables to determine if they moderate treatment effects such as parenting behaviors, family and neighborhood characteristics, and parental and child psychological functioning.

We will also assess putative nonspecific predictor variables that may have a main effect on outcome that is equal across groups, but that have no interactive effect with treatment.[14] In RCTs, these are variables that are not expected to have an interactive effect with the maintenance treatment, but rather a significant main effect (i.e., predict treatment response equally in the three treatments). Hence, we will examine the general predictive effects of collective baseline variables on outcomes.

Mediator Variables

In order to better understand how and why SFM+ works, we propose additional exploratory examination of treatment mediators. In RCTs, a treatment mediator is a variable measured during the treatment period that changes along with treatment and provides some indication on how or why the treatment works; such variables are correlated with a treatment's efficacy.[14] The hypothesized mechanism of SFM+ is improving parental and peer support for child healthy behaviors and on

increasing family utilization of neighborhood resources that promote physical activity and healthy eating as well as increasing the use of self-regulation strategies. We also hypothesize that the HIGH group (as compared to the LOW group) will produce better outcomes through increasing adherence to treatment targets (e.g., frequency of skills usage, utilization of treatment skills across a range of contexts, self-monitoring sufficiency). In addition, the Environment Questionnaire (ENV), which includes adherence questions, will be used to assess change in socio-environmental factors and self-regulatory behaviors, as well as frequency of skill usage and use of skills across contexts. Brief mediational assessments will be conducted every two months during the maintenance phase and at 18 month. These assessments will primarily consist of a subset of questions from the major assessments, with an additional set of new questions related to each treatment. Mediational assessments will be completed at regularly scheduled treatment sessions and will take approximately 10-15 minutes to complete. As part of the mediational assessment, a brief Treatment Expectations Questionnaire will also be completed.

Assessment Protocol

During the screening period, a clinician will describe the study, answer questions concerning the study, obtain informed consent, and assess potential participants. The initial assessment will involve measurement of child and parent height/weight, collection of basic demographic information and screening for exclusion criteria via parent reports of child and parent weight and dieting history, current medical problems, and current psychiatric treatment. Additional screening for reading level and current level of psychological functioning, including eating pathology, will be conducted as needed. Participants who meet all criteria and consent to participate will then be asked to return to complete the remaining baseline measures.

Assessment Instruments

Body Composition and Health Related Measures. In order to minimize participant discomfort, the decision was made to use the following, non-invasive measures of health related outcomes. (i) *Height and weight*. Child and parent weight will be assessed at each major assessment and at weeks 8, 16, 24, and 32 during the maintenance phase by a calibrated electronic scale. Height will be assessed using a stadiometer, calibrated in 1/8-inch intervals. Staff will be trained to accurately measure height and weight. On the basis of the height (in centimeters) and weight (in kilograms) data, three measures of relative weight will be calculated: BMI (weight in kg/height in m^2);[15] percent overweight (percentage actual BMI is above the median BMI for the child's age and sex as provided in CDC 2000 growth curves);[16] and BMI z-scores (calculated using CDC growth curves and accompanying procedures). (ii) *Dual-Energy X-ray Absorptiometry (DXA)*. As an indicator of adiposity, children's body composition will be assessed via a whole-body DXA scan at each major assessment (0, 4, 12, 18, and 24 months). Both clinical sites have state-of-the-art DXA machines for this purpose. DXA provides a validated measure of fat and lean mass in children and adults over time, an added benefit beyond weight and BMI.[17] Additionally, DXA is a noninvasive and brief procedure, taking only a few minutes to complete. Each site's DXA machine will be regularly calibrated by using of phantoms of known composition and the same machine will be used for all within-site participants. (iii) *Waist circumference*. Children's waist circumference will be measured at each major assessment (0, 4, 12, 18, and 24 months). Assessors will be trained to make this measurement accurately and reliably to the nearest 0.1 cm using a standard tape measure placed snugly around the largest part of the abdomen, laterally above the ilium, while the child is standing; three measurements will be taken and averaged. Increased waist circumference is a known marker of increased disease risk, and is taken briefly and non-invasively. (iv) *Bioelectrical Impedance Analysis (BIA)* will be used as an additional measure of body composition for children. Families will be reminded of pre-test guidelines: no eating or drinking within 4 hours, no exercise within 12 hours. BIA will be measured with a commercial instrument (Quantum X, RJL Systems, Clinton Township, MI). All children will be measured via a 4 electrode arrangement while lying on a portable examination table/mat.

Screening / Demographic Information. (i*) Modified Hollingshead Demographic Questionnaire (DEM)*. A modified version of the Hollingshead demographics questionnaire will be used to assess class, socioeconomic status, race, and ethnicity. In addition, the (ii) *Ethnic Ancestry Questionnaire (EAQ)* will be used to collect more detailed information on ethnic origin. This questionnaire has been added in response to recent demand for a more in depth analysis of ethnic origin and geographic origin. Parents will have the option of completing this questionnaire on behalf of their child if they would like to provide information beyond the standard NIH guidelines on race and ethnicity. (iii) *Scale of Subjective Social Status (SSQ)* was developed to capture a participant's perception of their social status. The scale consists of a pictorial representation of a "social ladder" and asks participants to place an "X" on the rung on which they feel they stand. The child will complete this measure as an indication of his/her perception of social status. *(iv) Parent and Child Qualitative Screening Interviews* will be conducted to determine if the treatment program is appropriate for each individual family and to identify any issues that may interfere with the family's ability to attend treatment sessions.

Energy-Balance Behaviors. (i) *24-hour dietary recall*. Child intake will be assessed with 3, 24-hour dietary recalls at each major assessment point (months 0, 4, 12 and 24), on 3 days, preferably non-consecutive randomly selected days. Dietary practices vary by time of week,[18] so these phone interviews will be scheduled for both weekdays and weekends. Twenty-four hour recall is considered the gold standard in adults,[19-22] and has been validated against the doubly-labeled water method for energy intake in young children.[23] All interviews will be conducted by trained staff at the Nutritional Research and Analysis Team at Cincinnati Children's Hospital using the Nutrition Data Systems for Research (NDS-R) nutrient calculation software;[24] NDS-R is a computer-based software application that allows for direct entry of dietary data in a standardized fashion. The multiple-pass phone interview technique will be used to prompt for complete food recall and descriptions,[23] and the Posner

2-dimensional food portion visual aid will be used to assist in portion size estimation.[25] The participating parent, and child if needed, will report on the child's intake. In order to complete these recalls, the study team will need to share minimal contact information for each participating family, including names and telephone numbers, to Cincinnati Children's Hospital at each major assessment point. Parent intake will be assessed using the *National Cancer Institute's (NCI) Multi-factor Screener*, a self-report measure of approximate intakes of fruits and vegetables, percentage energy from fat, and fiber. The screener asks respondents to report how frequently they consume foods in 16 categories and about the type of milk consumed. (ii) *Activity monitor*. Child physical activity will be assessed by the Actigraph accelerometer. The Actigraph measures moderate and vigorous physical activity, and is reliable and valid in children[26,27] and adults.[28] The epoch period will be set to 30 seconds, as children's activity often occurs in short bouts. Periods of moderate and high intensity physical activity can be identified by locating relatively high rates of movement for extended periods of time (e.g., 20 minutes) and using the established intensity cut-points. Participating children will wear the Actigraph for seven consecutive days, which is sufficient to obtain an assessment of habitual physical activity.[26,27] Trained survey staff will instruct participants on wearing procedures and completing a log to record the times they did not wear it (e.g., during sleep). Each family will complete an *Accelerometer Log* throughout the week to indicate when the child was wearing the activity meter and when he/she was not. They will also indicate when the child wakes up in the morning and when he/she goes to sleep. This information will be used to supplement the data from the activity meters. Parent physical activity will be assessed using the International Physical Activity Questionnaire (I-PAQ). The I-PAQ covers four domains of physical activity: work-related, transportation, housework/gardening and leisure-time activity. The questionnaire also includes questions about time spent sitting as an indicator of sedentary behavior. In each of the four domains the number of days per week and time per day spent in both moderate and vigorous activity are recorded. (iii) *Sedentary Behavior Scale (SED)* will be completed by parents to measure the amount of time the parent and the child spend doing certain types of sedentary behavior (e.g. watching television, playing computer games) each day.

Psychosocial Functioning. (i) *Achenbach Child Behavior Checklist-Parent Version (CBCL*). The CBCL[29,30] will be completed by the parent to assess a broad range of child psychological functioning, including child social problems. The CBCL has demonstrated good reliability and validity.[29,30] (ii) *Brief Symptom Inventory (BSI)*. Parents will complete the BSI, a 53-item self-report inventory of adult psychological functioning that produces an overall global index of psychopathology and 9 primary symptom domains, at each assessment point. The BSI has good internal consistency and is highly correlated with the more lengthy Symptom-Checklist-90-R (SCL-90-R).[31] (iii) PRIME-MD Screening Questionnaire and Interview. The PRIME-MD targets five basic mental health areas: mood, anxiety, somatoform, and eating disorders and alcohol abuse. The instrument consists of two basic components: a one-page screening questionnaire completed by the parent during the orientation session and a 12-page clinical interview, which will be conducted during the screening session only if the parent endorses any items on the screening questionnaire. (iv) *Eating Disorder Examination-Questionnaire (EDE-Q/YEDE-Q)*. The EDE-Q[32] and YEDE-Q (youth version) will be used to assess eating pathology in children and parents at each assessment. The EDE-Q assesses the full range of eating disorder attitudes and behaviors via four subscales (Restraint, Eating Concern, Weight Concern, and Shape Concern) and a global severity score, all of which appear to have adequate internal consistency and test-retest reliability.[33,34] Studies in both adults and children support the use of the EDE-Q as a screening measure for eating pathology, as it shows good agreement with the "gold standard" Eating Disorder Examination in its measurement of eating disorder behaviors (e.g., binge eating, compensatory behaviors)[32,35-38] and has a low rate of false negatives.[35,39] Due to the ages of children in the study, parents will also be asked to complete a brief adapted version of the EDE to report on child eating behaviors. (v) *Pediatric Quality of Life (PedsQL) Inventory*. Parents and children will complete the 23-item generic core measure of the PedsQL,[40,41] which assesses health-

related quality of life in children and adolescents in the areas of physical, emotional, social, and school functioning. The PedsQL appears to have good reliability and validity.[40] (vi) The *Child Eating Disorder Examination (ChEDE) – Overeating Section Only*, a widely-used gold-standard diagnostic interview for the assessment of eating behavior in youth, will be administered to children. To minimize participant burden, only the section assessing aberrant eating episodes will be administered, which asks children to describe episodes in the previous 28 days and 3 months in which they experienced overeating and/or loss of control. (vii) On the *Child Eating Behavior Questionnaire (CEBQ)*, parents will report on various aspects of their child's eating. The CEBQ is a 35-item instrument which yields 8 subscales: responsiveness to food, enjoyment of food, satiety responsiveness, slowness in eating, fussiness, emotional overeating, and desire for drinks. The CEBQ has good internal validity and test-retest reliability among parents of young children. (viii) The *Emotional Eating Scale for Children (EES-C)* is a 25-item self-report measure used to assess the urge to cope with negative affect by eating. Children will rate their desire to eat in response to each emotion on a 5-point scale (No desire, Small desire, Moderate desire, Strong urge, and Overwhelming urge to eat). The EES generates three subscales reflecting the urge to eat in response to anger/frustration, anxiety, and depression. (ix) *Coping with Teasing Scale (CTS)* is a child-report measure that examines the adequacy of children's responses to teasing. (x) *Short Mood and Feelings Questionnaire (SMFQ).* Children will complete this report of depression symptoms, which has been demonstrated to be a brief and reliable measure of depression in youth. (xi) *Screen for Child Anxiety Related Emotional Disorders (SCARED).* Children will complete this report of anxiety symptoms, which has been demonstrated to be a reliable and valid screening measure of anxiety in children and adolescents. (xii) *Child Dietary Self-efficacy Scale* (CDSS) will evaluate children's self-efficacy in choosing healthy, low-fat foods. (xiii) *Self-efficacy Scale for Physical Activity (SESCPA)* will examine children's perceived self-efficacy in overcoming barriers to achieving weight goals and developing positive alternatives to unhealthy habits. (xiv) *Loss of Control Eating Scale (LOC-ED)* scale will be used to measure the presence or absence of loss of control eating episodes in children. For children who report loss of control overeating, they are asked to report the presence or absence of various qualitative aspects that may occur during those episodes.

Socio-environmental Influences. (i) *Environmental Questionnaire (ENV)*. Parents will complete a self-report measure of environmental factors that may influence healthy-related behaviors, including the presence and use of recreational electronic equipment (e.g., number of TVs and computers in the home, enforcement of rules to limit usage of electronic equipment), access to and use of activity items in the home, access to and use of neighborhood resources promoting physical activity (e.g., school play area, parks, recreation centers), neighborhood characteristics (e.g., neighborhood safety), the availability and child's consumption of a range of foods in the home, enforcement of family meal rules (e.g., television access during meals, frequency and timing of snacks and meals, eating meals together), and family meal structure (e.g., meals cooked at home or take-out, food selection, and portion size management). This measure was adapted from the Environmental Analysis Form, an interview-based assessment used in Dr. Epstein's previous trial, "A Behavioral Economic Approach to Childhood Obesity" (HD 03792). To decrease participant burden and time required for the assessment, this measure will be administered in a self-report format. (ii) *Children's Report of Parental Behavior Inventory (CRPBI).* The CRPBI[42] will be completed by the child at each assessment point in order to assess their perceptions of the participating parent's parenting style and behavior. These measures have established psychometric properties[43] and are used to investigate children's perceptions of the parents' child-rearing behavior on three dimensions: acceptance vs. rejection, psychological autonomy vs. psychological control, and firm control vs. lax control or discipline. (iii) *Child Feeding Questionnaire (CFQ).* The CFQ will be used to assess parents' perceptions and concerns about child obesity, in addition to child feeding attitudes and behaviors. It consists of 24 items evaluating parents' use of control in feeding their children, concerns about their children's weight status and eating behaviors, and perceptions of their own weight when they were

children. (iv) *Social Support and Eating Habits/Exercise Survey (SSEHS/ES)*. The SSEH/ES[44] will be completed by the parent and child at each assessment point to evaluate their perception of parental and peer support for healthy eating and activity. The SSEHS/ES has good criterion and discriminant validity for adults and has been modified for use among children. (v) The *Neighborhood Environment Walkability Scale (NEWS).* Parents will complete the NEWS as a measure of perceived attributes of the local environment related to physical activity. Concepts and subscales are based on variables believed to relate to walking and other physical activities that are discussed in the urban planning literature. The questionnaire assesses the following environmental characteristics: a) residential density; b) proximity to nonresidential land uses, such as restaurants and retail stores (land use mix–diversity); c) ease of access to nonresidential uses (land use mix–access); d) street connectivity; e) walking/cycling facilities, such as sidewalks and pedestrian/bike trails; f) aesthetics; g) pedestrian traffic safety; and h) crime safety. The NEWS will be used as a measure of how the neighborhood environment relates to physical activity in families and how environmental factors may influence response to weight-loss treatment. (vi*) Starting a Program (SAP).* The Starting a Program questionnaire will be completed by parents to examine several important concepts related to beginning a new treatment program. Questions will examine whether or not parents have discussed their child's health and participation in this program with a doctor, if they have previously attempted to adopt healthy behaviors, and if they feel confident in their ability to change. (vii) The *Network Support for Healthy Behaviors Interview (NSHB)* was adapted from the Important People initial interview, originally designed for the purpose of gathering information pertaining to an alcohol abuser's social support system. The present version is focused on assessing the participant's network on two dimensions: 1) establishing the participant's social network and 2) assessing the support of network members for the participant's behaviors that could impact weight loss or gain. Parents and children will complete the interview. In addition, parents are also asked to report on their child's social network, especially concerning constructs that the child may not be able to accurately report. Participants are queried regarding the members of their network, including their relationship to each person, the amount of contact they have with the person, and how often they see the person. Then the subject is queried regarding each person in the network: their weight status, their frequency of healthy and unhealthy behaviors (e.g., eating habits, activity), and their response to/support for the participant's coming to a weight loss group. The parent is also asked to report on whether some relationships (e.g., friendships, other children such as relatives not in the immediate family) are "mutual."

Reinforcing Value of Food. (i) The *Relative Reinforcing Value of Food (RRV) Task* will be administered to assess child and parent food reinforcement. This assessment has been validated in adults against the computer-generated concurrent schedules paradigm assessing the RRV of food and it has been successfully used in children as young as age 7. On the RRV of Food Task, participants are asked to indicate their preference for completing work to obtain reinforcers (e.g., high-fat snack, money, fruits and vegetables, or physical activity). The hypothetical amount of work required to obtain either reinforcer consists of clicking a handheld tally counter a prescribed number of times. The primary outcome variable obtained from the RRV of Food Task is the switch point—that is, the item number at which the individual switches from choosing the food reinforcer to choosing the other reinforcer. (ii) The *Food Purchasing Questionnaire (FPQ)* was recently developed by Epstein and validated against the computerized assessment of food reinforcement described above. Participants are asked to respond to the following question: "How many portions of _____ (*preferred snack food*) would you consume if they were ____ each at the following 19 prices?: Zero (free), $0.01, $0.05, $0.13, $0.25, $0.50, $1, $2, $3, $4, $5, $6, $11, $35, $70, $140, $280, $560, $1,120." The prices are presented in ascending order. Similar to the RRV of Food Task, the primary outcome variable obtained will be the switch point (i.e., the last price at which consumption was greater than zero). Both the parent and child will complete these measures. (iii) *Delay choice questionnaire and Money Choice Questionnaire (DCQ/MCQ)* will be completed by the

child and parent, respectively, as a measure of one's ability to delay gratification (e.g., impulsivity). Both measures ask participants to choose between a smaller, immediate amount and a larger, delayed amount to determine one's level of impulsivity. Ability to delay gratification has been associated with a high reinforcing value of food and unhealthy eating behaviors that contribute to child obesity.

Adherence. (i) *Attendance*. The number of sessions attended by the participants will be monitored to provide an objective measure of treatment adherence. (ii) *Adherence Questionnaire in the Environmental Analysis Questionnaire (ENV)*. In addition, children and parents will complete a self-report measure assessing their learning and integration of treatment material into their daily lives and across contexts (e.g., home, peer, neighborhood). Specifically, at maintenance weeks 8, 16, 24, and 32, children will report on the frequency with which they utilize specific self-regulation (e.g., returning to weight loss behaviors when weight goes above maintenance range) and social support skills (e.g., making time with peers more physically active) and the number of contexts in which they have practiced this skill (e.g., home, school, neighborhood). Parents will report on how they create environments which support healthy eating and activity (e.g., using positive parenting behaviors, frequency of discouraging sedentary behavior) and the number of contexts in which they have provided such support (e.g., home, neighborhood). As this measure will be completed by all groups, questions related to the health education control treatment will also be included. (iv) *Assisted Recall of Social Context*. In replace of Ecological Momentary Assessment (EMA), questions evaluating the social context around eating and physical activity will be administered using assisted recall techniques as part of the 24 Hour Food Recall Interviews. Based on previously used EMA, these questions will be used to provide a more objective and ecologically representative assessment of children's adherence to dietary and physical activity behaviors, as well as their association with various socio-environmental contexts (e.g., at home vs. parks, with family vs. with friends). Children will be asked to recall details of eating episodes and bouts of sedentary and physical activity that occurred during the previous day (i.e., weekday afternoons after school and throughout weekend days) for three days at each assessment time point. By incorporating these questions within the 24 hour food recall interview, this procedure will help to reduce participant burden.

Genetics. *Saliva sample collection*. Saliva samples will be collected from children and parents to determine if the presence of the TaqA1 allele (A1+) is associated with obesity-specific psychological characteristics (e.g., high food reinforcement) obesity-related behaviors (e.g., overeating), and response to the treatment program. Participants will provide 2-3 ml of saliva for DNA analysis. Participants will be asked to spit into a plastic vial. DNA will be extracted from the samples using a commercially available genomic DNA quick preparation kit (Oragene DNA®), yielding 110 µg of DNA at a concentration of 20-200 ng/µL. After DNA purification, each sample is assigned an accession number and stored at –20°C. All samples will be solely identified by a study ID number. Should a participant withdraw his/her consent from this genetic testing, the samples will be immediately destroyed.

Suicidal Ideation. Although we do not anticipate any instances of suicidal ideation, all study staff will be trained on a standard protocol in case this situation does occur during the screening process. If a parent reports suicidal ideation while completing the PRIME-MD interview, the interviewer will administer a standard set of follow-up questions to determine if the participant's level of risk is imminent. Participants may have occasional thoughts about "being better off dead" or passing thoughts about suicide, but deny any desire, intent, plans or means to attempt suicide, nor have they dwelled on thoughts of death, dying, or suicide in the past month. If this is the case and risk of a suicide attempt appears minimal, the interviewer will provide the parent with a list of referrals for community mental health services in the area and encourage the parent to seek further treatment. If the parent reports that he/she has been considering suicide (including has a plan), and/or has made a suicide attempt in the previous month, the level of risk will be considered imminent. If a participant indicates that he/she is actively suicidal, the project coordinator will immediately encourage the

participant to go to the nearest emergency room and/or the project coordinator will call campus security (2-HELP) and ask them to escort the participant to the emergency room. In addition, several clinical psychologists and psychiatrists are on staff and will be available for consultation in case this situation does occur. Participants will be notified on the informed consent that the investigators may be required to share their information if they have reasons to be concerned about the participant's safety.

D.5. Details of Follow-Up

Every effort will be made to retain as many participants as possible throughout follow-up. During the initial interview, participation in follow-up assessments will be explained. The interviewer will describe the value of the study and each participant's importance to the project. Randomized participants will be encouraged to complete all assessments, regardless of treatment compliance.

How Participants will be Tracked

At baseline, the participating parent will be asked to complete a follow-up continuity form with their home and work contact information, and the contact information of two or more relatives/close friends who may be called if the participant moves without notification. At each follow-up interview a routine inquiry will be made about any existing or anticipated changes in contact information. Using such methods, Dr. Wilfley has been able to contact and assess 90% of the 105 participants in her current NIMH-funded Binge Eating Disorder treatment trial at post-treatment and two-year follow-up. Similarly, in another study[45] comparing two different therapies for patients with BED, the retention rate was 90% at 12-month follow-up.

How Dropout will be Minimized

In our original study, we incurred a relatively high treatment dropout rate (25%) during the weight loss phase. Thus, in the current proposed study, we will employ more aggressive strategies to minimize dropouts during and after the course of treatment. These include strategies that have been well-documented as some of the most effective retention tactics in behavioral intervention trials.[46] Specifically, we will provide an in-depth pre-treatment screening interview designed to instill a sense of ownership and commitment to the treatment by discussing participant expectations and clarifying treatment goals. Based on our experience in previous trials, we plan to utilize a proactive approach to increase retention that includes strategies for all participants as well as those with sub-optimal or poor performance. To this end, flexible appointment times and locations (i.e., home-based assessments) will be available, with make-up sessions in person or by phone as needed, and to minimize dropout while not preventing participation based on financial constraints, participants will be provided with reimbursement for transportation as needed. We will monitor adherence to treatment and assessment sessions, which will highlight participants who may be difficult to retain. Such participants will be encouraged to strategize with interventionists, methods for overcoming barriers to adherence, enhancing their perception of treatment as an interactive process. During the maintenance phase, we will also provide small attendance prizes to encourage attendance. Prizes will be small in value (approximately $10) and will be related to the content of the treatment (e.g., encourage physical activity or healthy eating as a family). Each family that attends the session will be given a raffle ticket to enter the drawing and at the end of each session, a winner will be randomly chosen. Dr. Perri and his research team have used attendance prizes in the past and have found them to be a helpful strategy to increase attendance. Further, Drs. Perri and Epstein have extensive experience with these issues and will provide consultation about retention throughout the study.

Schedule and Structure of Continued Contacts

To increase retention from 12 to 24 months all maintenance condition (CONTROL, LOW and HIGH) participants will have the opportunity to participate in the continued contact phase of the study. The LOW and CONTROL conditions will receive the same number of contacts. The HIGH and LOW condition will only differ in dose, matching the dosing during the maintenance treatment. The schedule of continued contacts for the CONTROL and the LOW conditions is 6 contacts delivered

over 12 months, while it is doubled for the HIGH condition: 12 contacts over 12 months. This contact will be achieved by two means for all maintenance conditions. Participants in the LOW and CONTROL conditions will complete 4 contacts by phone/e-mail. The remaining two contacts will occur in person during the 18 and 24 month assessment visits. Participants in the HIGH condition will complete 10 contacts by phone/e-mail, and the remaining two contacts will occur at the 18 and 24 month assessment visits. Both HIGH and LOW will be sent support cards, which summarize the discrete skills of the socioecological treatment model used throughout the maintenance phase and will be content used during the continued contact phase. HIGH and LOW will be sent the support cards using an on-line survey company: Survey Monkey.

COMPASS research staff will send participants (HIGH and LOW) an email containing a link to Survey Monkey providing them the opportunity to log on and complete the Support Card in survey form. In this email, participants will be given a random number assigned to them and will be requested to enter it as part of completing the Support Card. The number will allow us to link responses to participants. The responses accessed via Survey Monkey and the link between the random number, and the participant's name will be stored on Washington University's secure server and only research staff will have access to this information. Survey questions and responses are kept in strict confidence and used in compliance with legal requirements. User information is protected using both server authentication and data encryption, ensuring that user data is safe, secure, and available only to authorized persons. Survey Monkey does not disclose survey questions or responses unless permitted or requested. Permission will not be granted to disclose any survey questions or responses to a third party.

Each time the Support Card is sent out, staff will review the responses provided by participants, discuss their progress, provide feedback and set goals for the upcoming two months via telephone or email. Participants who complete the support card will be entered into a drawing for a prize; see details below. Although both SFM+ conditions will complete support cards, the HIGH participants will be given an opportunity to receive additional feedback on their support card and subsequent goals during their supplementary contacts.

In both the HIGH and LOW conditions, participants will be encouraged to use SparkPeople, an on-line monitoring service that allows individuals to log and track their food and input their weight on a weekly basis (behaviors used during the treatment phase). Research staff will assign usernames and passwords, and this account information will be sent to each participant via 2 secure messages from the study's outlook e-mail. Participants' usernames and passwords will not contain anything linking the account to their name, study ID or any other identifying information. Each participant will be assigned a random identifier number not associated with their participant ID. The username will include this new identifier allowing us to link a participant to their responses. The participant's username and password will be set up by study staff using the participant's e-mail address they provided during the treatment phase of the study. SparkPeople has been used in other evidence based weight-loss treatments. SparkPeople uses multiple firewalls and levels of physical security to protect the personal information that participants would input on the site. They encrypt passwords when they are submitted in order to protect from unauthorized access or disclosure. Staff will have access to the information participants put onto the website. Once per week staff members will log onto the participant's account and print reports of the participant's weight and eating. These reports will be stored in a locked file cabinet in a locked office in Dr. Wilfley's lab, accessible only to research staff. The link between the random identifier assigned to each participant will be kept on Washington University's secure server, accessible only to Dr. Wilfley and study staff.

For their continued contact, the CONTROL condition will receive an article related to study content which was covered during the treatment phase. CONTROL participants will be sent 3 questions related to the article. If a CONTROL participant answers the questions, they will be entered into a drawing for a prize; see below. The participant does not need to answer the questions correctly to be entered into the drawing.

Participants across all maintenance conditions who provide their completed support card (HIGH and LOW) or answer the questions related to the mailed article (CONTROL) will be entered into a drawing for a gift card; drawings will be held approximately every two months. Each participant will have an equal chance of winning a gift card. Prizes will be small in value (approximately $10) and will be related to the content of the treatment (e.g., encourages physical activity or healthy eating as a family). The information gathered from participants during continued contact will not be used for data and is only used as a treatment tool to retain participants. The only data kept will be the amount of contact the family has (i.e. dose).

D.6. Data Analysis Plan

Randomization

At the end of FBT, children will be stratified by age, race/ethnicity, sex, social problems, and change in percent overweight and then randomly assigned to one of the three maintenance conditions (i.e., CONTROL, LOW, HIGH), using a web-based randomization tool provided by the project statistician. The web-based tool will provide separate randomization streams for each sex and change in percent overweight group, and will be available from any Internet-linked location. The streams will be blocked with varying numbers of cases (3,6,9), so that prediction of the next condition to be assigned will not be possible, but each group will be approximately balanced regardless of presentation rate.

Statistical Power Analysis

The power analysis was performed using the SAS/IML Powerlib 2.03 macros.[47] These power analyses were based on the time points proposed in the original 5-year proposal. Treatment was shortened because funding was only provided for 2 years, but we maintained the effect size estimates and resulting sample size estimates for the trial. For these computations, we assumed α=.05, with a high correlation (r=0.85) between different measurements of a given variable at different time points, and that all tests were 2-sided. The correlations and standard deviations for power computation were estimated using data from our previously completed study.

Table 3. Expected Weight Loss Trajectory for Change in Percent Overweight and SD's for Power Estimates

	Time Point (month)			
Condition	0	6	18	30
CONTROL	0	-15	-7	0
LOW	0	-15	-10	-6
HIGH	0	-15	-15	-12
SD	10	12	12	12

All analyses were performed as repeated measures. For the power computation, estimates of treatment effects over time and variation from our previously completed study and predictions for the present study for percent overweight were used. The time points for measurement are post-weight loss intervention (4-month), end of maintenance treatment (12-month) and at 1-year (24-month) follow-up. **Table 3** presents the expected outcomes (percent overweight change) for the CONTROL, LOW, and HIGH groups. Expected change scores are based on weight outcomes from our previously completed study. Predictions for CONTROL are based on outcomes for the no-treatment control group (NTC), and predictions for LOW and HIGH are in part based on results from SFM in our previous study. These reflect our prediction that the LOW group will regain some of the original lost weight, while HIGH will maintain most of this relative weight loss through long-term follow-up; both groups will have success in comparison with the control group. Of note, predictive biosimulation analyses of the expected relative weight trajectory of children over time in HIGH SFM+, as conducted by Pharsight, Inc. were consistent with these original projections. Thus, statistical models based on the data from our previous trial supported our selected effect sizes **(see Table 4)**. ***For this reason, we have maintained our predicted weight loss trajectories and power estimates from the previous submission*.**

Table 4. Power Estimates for Different Weight Loss Trajectories

Comparison	55/ group	75/ group
Trajectory 1		
Content: CONTROL v LOW	.98	.99
Dose: LOW v HIGH	.98	.98
Trajectory 2		
Content: CONTROL v LOW	.98	.98
Dose: LOW v HIGH	.79	.90

To examine the two primary aims, specific planned contrasts will be used. Contrast 1 represents a partial interaction contrast to address Specific Aim 1 (efficacy: CONTROL vs. LOW, 4-month vs. 24-month follow-up). Contrast 2 is a partial interaction contrast used to address Specific Aim 2 (dose: LOW vs. HIGH, 4-month vs. 24-month follow-up). Given our expected outcome patterns shown in **Table 3** and the assumptions for the power analysis, power to detect the expected effects is larger than .90 with 75 participants per group. Assuming a higher than expected attrition rate (e.g., only 55 completer participants per group), power to detect these effects remains above .90. In **Table 5** we have a slightly altered scenario, in which a change of -2 is predicted for the CONTROL group and a change of -8 is predicted for the LOW group at the 24-month point. For this scenario, power for the LOW vs. HIGH contrast is reduced to .90 with 75 participants per group and to .79 with 55 per group **(see Table 4)**. Thus, to achieve a minimum statistical power above .80 for all key hypothesis tests even if the LOW group is assumed to have more than expected maintenance of weight loss, we will need at least 55 participants in each group to complete follow-up; thus, our total planned 24-month sample will be at least N=165.

Table 5. Alternative Weight Loss Trajectory

	Time Point (month)			
Condition	0	6	18	30
CONTROL	0	-15	-7	-2
LOW	0	-15	-10	-8
HIGH	0	-15	-15	-12
SD	10	12	12	12

In sum, given our procedures to minimize attrition from FBT and maintenance groups, we anticipate an attrition rate of no more than 20% (48/240) during the weight loss treatment phase (between 0 months and 4 months) and no more than an additional 17% (41/240) of the randomized sample during the maintenance and follow-up phases (i.e., between 4- and 24-month follow-up) for a total attrition rate of 34% (82/240) of the original 240 participants. This level of attrition requires 192 participants (64 per group) at randomization in order to retain 165 participants (approximately 55 per group) and have sufficient power to detect differences at the 24-month follow-up. Thus, a total sample size of N=240 will be recruited, with 20% attrition leaving 192 participants for randomization. Given that most RCTs are underpowered,[48] we have been conservative in our calculations, ensuring that we will have adequate power to detect clinically significant effect sizes.

General Data Analytic Approach

To examine the short- and long-term efficacy of the maintenance interventions, mixed-model, repeated measures ANOVAs (RMANOVA) will be conducted on treatment and secondary outcome measures. Such methods are state-of-the-art statistically, and allow the analysis of all ANOVA-like questions, while ensuring that all measured values are used in the analysis. Most importantly, mixed-model methods enable the use of more appropriate covariance patterns between different dependent values. To protect the family-wise Type I error rate at α=.05 when conducting unplanned multiple follow-up tests, proper adjustments will be made (e.g., Tukey). In all analyses of intervention outcomes, attrition will be dealt with based on the intention-to-treat rule consistent with standard practice in most clinical trials. That is, all possible values will be included in final analyses, and no cases will be deleted due to missing values. This strategy yields conservative estimates of treatment effects based on all participants entering the treatment program rather than effects based on a subset of participants completing the intervention. This analysis includes all randomized cases to the maximum extent that data are available. In addition, analyses will be conducted in which we use the baseline (0 month) value carried forward (i.e., assumption of return to baseline for assessment dropouts) in order to assess that the pattern of findings remains the same. This accepted method of imputation provides the most conservative estimate of treatment effects. Lastly, as a secondary and exploratory analysis, we will perform a "per-protocol analysis" using only participants who have attended a minimum adequate number of sessions. As is common practice in behavioral treatment research,[49,50] we will categorize participants who have attended at least 80% of sessions as

"completers" for inclusion in this analysis. Statistical analyses will be conducted using standard statistical packages, including SPSS, SAS, and STATA, for personal computers, as appropriate.

Diagnostic Analyses

We will first conduct a series of preliminary analyses to examine equivalence among conditions and between sites after randomization. In these evaluations, we will examine patterns of missing values, presence of outliers, and distributional characteristics of variables. Missing values will be examined carefully to determine their causes and potential impact on subsequent analyses. For many analyses involving mixed models, missing values are dealt with in a natural manner, in that existing values are analyzed, and no observations are deleted due to missing values. If necessary, missing values will be dealt with through multiple imputation[51] and implemented in major data analysis programs (e.g., SAS, Solas, SPSS). We will also examine whether differential attrition occurred[52] among conditions and/or between sites. Differential attrition could have important implications on statistical analyses (i.e., modeling selection factors) and on the internal validity of conclusions regarding the causal nature of treatment effects. In particular, it is concerning when more participants drop out from the control condition than from the active treatment conditions. We will proceed with hypothesis tests after dealing with any existing problems and being satisfied that hypothesis tests are robust to violations of important assumptions. If necessary, appropriate transformations and/or alternative robust statistical analyses will be considered. In addition, it is possible that interventionists and treatment groups may introduce a significant source of variance in treatment outcomes. We will carefully investigate the presence of interventionist and treatment group effects before testing any hypotheses about treatment outcomes. If necessary, analyses will be modified to reflect interventionists or treatment groups as covariates. Analyses will also examine site differences. We do not expect site differences to occur, since adequate training and standardization should result in comparable results. To check site effects, baseline tests between sites will be performed. In addition, site X time X treatment condition interactions will be checked for main variables.

Analyses by Specific Aims

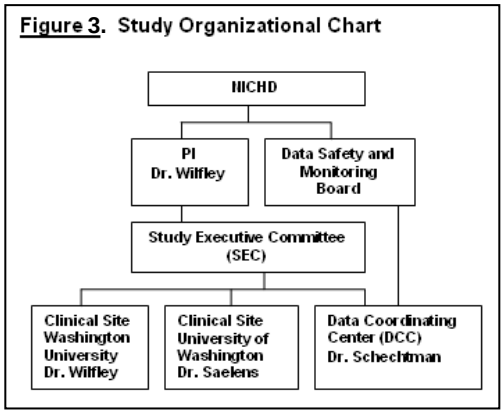
Primary Aim: Weight Changes. A 3 (Group: CONTROL, LOW, HIGH) X 3 (Time: 4-, 12- 18-, and 24- months) mixed-model repeated measures ANOVA design will be used for testing the hypotheses that the groups differ in percent overweight at the 4-, 12- 18-, and 24- month assessments. The main test will involve a Group X Time interaction. This will be followed by simple effects analyses and specific comparisons (as have been described above), examining group differences at the 4-, 12- 18-, and 24-month assessments. For these analyses, PROC MIXED in SAS will be used. These programs have been designed to handle general unbalanced repeated measure models, using mixed-model methods, where the imbalance is due to observations missing at random and different covariance structures for repeated measures can be used. Planned contrasts will be used to address the specific efficacy and dose aims. Specifically, the CONTROL and LOW groups will be compared to test the efficacy hypothesis, which states that the participants in the LOW group will have better maintenance of weight loss at months 18 and 24 (e.g., lower percent overweight at months 18 and 24). The LOW and HIGH groups will be compared to test the dose hypothesis, which states that the participants in the HIGH group will have better maintenance of weight loss at months 18 and 24. These contrasts will be performed at α=.05 and will also be performed using the mixed-model approaches.

Secondary Aim: Body Composition and Health-related Variables, Energy Balance Behaviors, Psychosocial Outcomes, and Socio-environmental Influences. Methods, analyses, and techniques similar to Specific Aim 1 will be used with secondary outcome variables (e.g., energy-balance behaviors, psychosocial functioning). All analyses will involve mixed-model methods. For variables that are not continuous, normally-distributed variables, appropriate GEE models will be used (using GENMOD in SAS).

Secondary Aim: Moderator, Mediator, and Non-Specific Predictors. To test the prognostic significance of social problems on change in percent overweight,[53,54] mixed-effects longitudinal regression models (either linear or non-linear) will be used.[55-57] These models are useful in

understanding relationships between variables when the predictors change over time. In these models, predictors, both time-invariant and time-varying, can be included, and evaluated to determine prediction of both primary and secondary outcome measures. These analytic approaches will be used to explore the effect of other potential moderators (e.g., psychopathology) and nonspecific predictors of outcome (e.g., child age, sex, and family SES) in order to determine for whom and under what conditions treatment works.

The final analytic procedure for detection of mediators is exactly the same as that for moderators. The difference is that before a variable can be considered a mediator, there must be demonstration that (1) it represents an event or change that occurs during treatment, not before; and (2) it is correlated with (and thus possibly a result of) treatment. The first requirement is satisfied by selecting as possible mediators only measures of changes occurring from the start of maintenance treatment. The second requirement uses the putative mediator as the dependent variable in an ANOVA with treatment as an independent variable. A statistically significant treatment effect must be demonstrated.



D.7. Organizational Structure

Dr. Wilfley will serve as chair of the Study Executive Committee (SEC) and will oversee the St. Louis clinical site. Members of the SEC include Dr. Saelens, who will oversee the clinical site at Seattle Children's Hospital; Dr. Schechtman, who will oversee the independent Data Coordinating Center (DCC) at Washington University; Dr. Perri, who will collaborate with the investigators on the adaptation of the extended weight-maintenance treatments and consult on the delivery of the weight management education control condition, and Dr. Epstein, will serve as an expert consultant regarding cross-site study and treatment implementation, assessment (e.g., home environment and ecological momentary assessment methods and analysis, and results dissemination. The DCC will report to the SEC. This organizational structure is illustrated by **Figure 3**.

Data Safety and Monitoring Board (DSMB)

The DSMB for this trial will be comprised of two clinicians with expertise in pediatric obesity, and a patient advocate, who will provide oversight and ongoing monitoring of participant safety and data integrity.

Study Executive Committee (SEC)

The SEC will be responsible for decision-making related to the overall scientific conduct of the study and monitoring the overall progress of the study to ensure timely study completion. Dr. Wilfley will develop the agenda and lead regular meetings throughout the study; she will also be the principal point of contact for the initial resolution of study-wide questions posed by the investigators and for the flow of information regarding the progress of the study. The SEC will be responsible for the final approval of the study protocol and any changes to the developed protocol, all of which will be documented in writing as part of the SEC minutes. The SEC will meet in person or by phone at six-month intervals during the first two years, alternating between the two treatment sites to discuss the day-to-day management of the study and evaluate the overall scientific conduct of the study, and to monitor the functioning of each clinical site, and the DCC. These meetings will be timed to coincide with the assessment/treatment workshops and training sessions. During the study start-up phase, there will be bi-monthly conference calls, which will become monthly thereafter. Additional calls will be scheduled as needed. In the third year, there will be two SEC meetings at Washington University to review follow-up assessments, data analysis, and preparation of results for publication.

Data Coordinating Center (DCC)

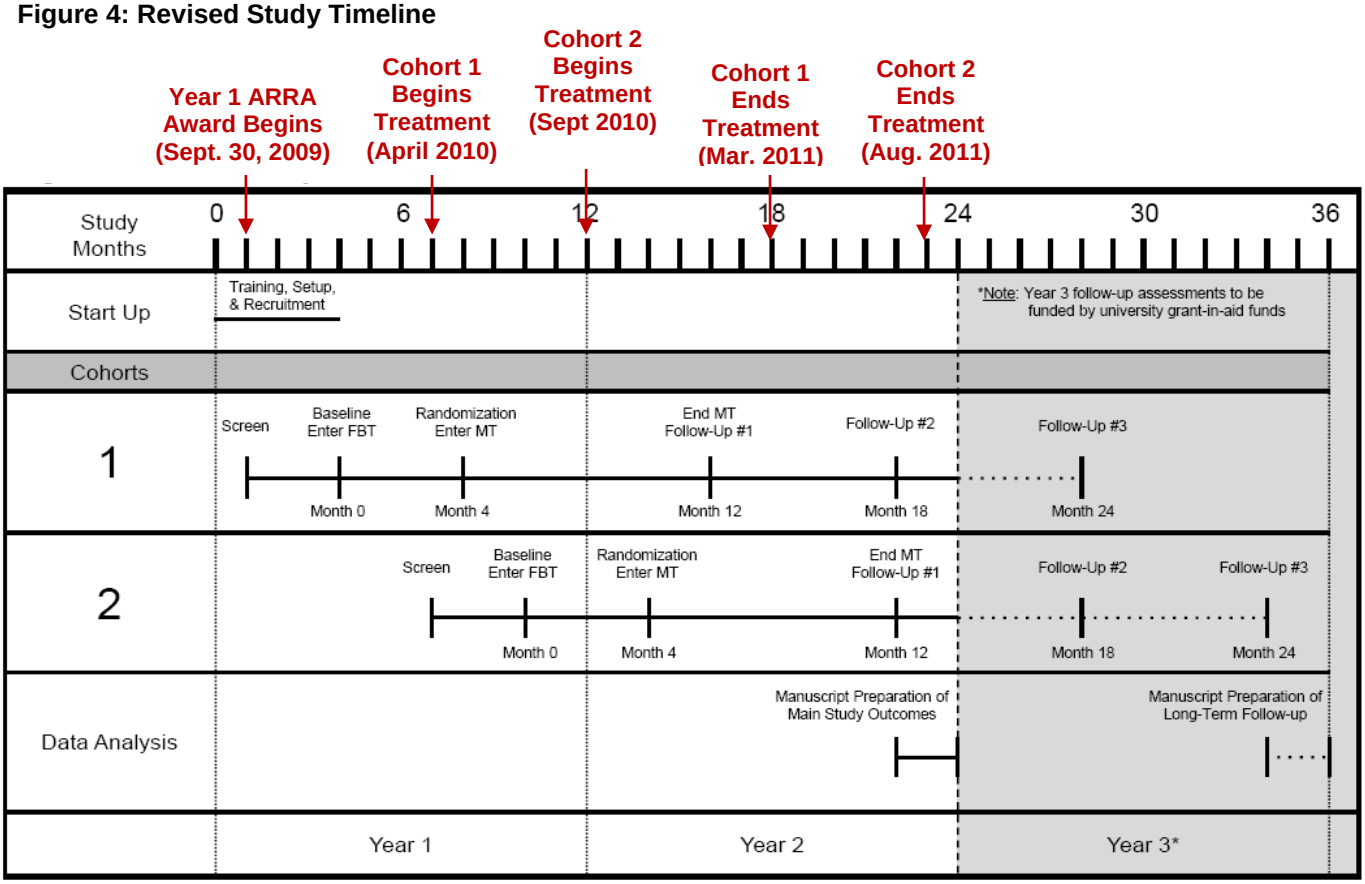
The DCC will be directed by Dr. Schechtman, a senior statistician who is part of the Division of Biostatistics at the Washington University School of Medicine. Both Dr. Schechtman and this division

have more than 25 years of experience running dozens of Coordinating Centers, Analysis Centers, Biostatistics Subcontracts for multi-site investigations, and large program projects. The DCC will oversee the implementation of the overall study operating procedures, data management and analysis, and assessment and treatment procedures. Study oversight responsibilities include maintaining the study manual of operations, the implementation of the randomization protocol, the safety and confidentiality of participant records according to HIPAA guidelines, and the production of study progress and data quality and adverse event reports for the DSMB. Two behavioral scientists, Drs. Stein and Welch, are well equipped to assist Dr. Schechtman in the implementation of procedures to ensure quality control across sites in the conduct of assessments and treatment. Dr. Stein will oversee training and ongoing annual certification/recertification of all assessors, as well as ongoing monitoring of adherence to assessment protocols. Dr. Welch will provide ongoing checks of treatment integrity (please see treatment integrity section above). These procedures will minimize any potential disadvantages of two centers conducting assessments and treatment by maintaining close attention to uniformity of assessment and treatment methods. Data oversight responsibilities include the development of a centralized data management system (including back-ups), data transfer and entry procedures, and the analysis for primary and secondary outcomes. Finally, as our requested budget is over $500,000 per year, the DCC will assure adherence to the NIH policy on data sharing. A de-identified data set will be made available to the research community following completion of the primary and secondary papers emanating from this data set. In accordance with the NIH Public Access Policy, copies of all accepted peer-reviewed papers will be posted on the NIH National Library of Medicine Pub Med Central website six months after the publication of the paper.

D.8. Timeline

The timeline for the study is shown in **Figure 4** (beginning after 3 months of initial study planning/set-up; note that month numbers refer to months after the start of the study funding). The anticipated start date is September 2009, beginning immediately with hiring, training staff on assessment and treatment protocols, and recruitment and screening for Cohort 1 (n=60 per site). Weight loss treatment will begin during month 4 and continue until the beginning of month 8, when Cohort 1 participants will be randomized to one of the three maintenance treatments. Maintenance treatment for Cohort 1 will occur during months 8-16. Follow-up assessments for Cohort 1 will occur at months 16, 22, and 28. Recruitment and screening for Cohort 2 (n=60 per site) will begin in month 7, and weight loss treatment will occur during months 10-14. At month 14, Cohort 2 participants will be randomized to maintenance treatment and maintenance treatment will occur during months 14-20. Follow-up assessments for Cohort 2 will then occur at months 22, 28, and 34. The remaining time will be used for data entry and analysis, preparation of papers for publication, and dissemination of study results **(see Figure 4, next page)**.

Figure 4: Revised Study Timeline



Note: FBT = family-based weight loss treatment; MT = maintenance treatment .
Participant recruitment, training of therapists and assessors, and preparation of intervention protocol will occur during months 1-4. A total of 240 participants (120 per site) will enter family-based weight loss treatment (FBT) for 4 months, followed by randomization to one of three, 8-month maintenance treatment (MT) conditions: (1) Low-dose SFM+, (2) High-dose SFM+, or (3) Health Education Control. To meet the overall study recruitment goal of 240 families by the end of Year 1, participants will be divided into 2 cohorts, where 120 participants (60 per site) will begin treatment in month 4, and the next 120 participants (60 per site) will begin treatment in month 10. For all participants, relative weight and associated outcomes will be assessed over a 2-year time period. These timepoints by month include 0 (baseline/pre-treatment), 4 (post-FBT/pre-MT), 12 (post-MT), 18 (6 months post-MT), and 24 (12 months post-MT). Follow-up assessments conducted in Year 3 will be funded by institutional grant-in-aid (for Cohort 1 at Follow-up #3, and for Cohort 2 at Follow-up #2 and #3). Data analyses and manuscript preparation will occur in months 22-24 (main study outcomes) and 34-36 (long-term follow-up).

E. HUMAN SUBJECTS RESEARCH

Protection of Human Subjects

1. Risks to Human Subjects

a. Human Subjects Involvement and Characteristics

This project involves participation of human subjects, including children with overweight or obesity and their families.

Inclusion Criteria:

The participating children will be between the ages of 7 and 11 and at or above the 85th percentile for weight. At least one parent of the participating child must have a BMI≥25. One parent must agree to attend all parent/child treatment meetings as the participating parent. For families in which one parent is obese, the obese parent will be encouraged to be the participating parent; if two parents are obese, the family will choose one parent to enter treatment. Though only the participating child and parent will be required to attend treatment sessions, all family members living in the household, including both parents and siblings, will be encouraged to participate indirectly by supporting changes in the family's lifestyle.

Exclusion Criteria:

Participants must be able to speak and comprehend English at a first-grade level. In addition, the participating parent or child will not suffer from a thought disorder, suicidality, bipolar disorder, or drug or alcohol dependence; will not have a physical disability or illness that prevents performance of physical activity at a level equivalent to a brisk walk or that places severe restriction on diet; will not be on a medication regimen that affects weight; and will not be involved in active psychiatric treatment for an ongoing problem that causes either social or occupational impairment. Additionally, parents (participating and nonparticipating) and children will not have an eating disorder (i.e., anorexia nervosa, bulimia nervosa, binge eating disorder) or have subclinical levels of eating disturbance (i.e., reporting key eating disorder behaviors of purging, fasting, or binge eating more than two times per month).[58]

Rationale for the Involvement of Children ages 7-11:

Adolescence is a critical period for obesity development, thus interventions targeting preadolescent children provide them with the skills needed to regulate their weight before they reach adolescence.

Collaborating Sites:

The two sites will include Washington University School of Medicine in St. Louis, MO, and Children's Hospital and Regional Medical Center in Seattle, WA. Both sites will be responsible for recruiting and screening participants as well as administering family-based behavioral weight loss treatment (FBT). Following FBT, participants (parents and their children) will be randomized into the three maintenance conditions. Both sites will also conduct follow-up assessments with their respective participants.

b. Sources of Materials

Research materials include standardized clinical interviews, self-report questionnaires, self-monitoring forms, tapes of interventionist sessions, accelerometer data, DXA Scans, waist circumference, and height and weight measurements. All measures are described in **section D.4**. Data will be obtained for research purposes only. All research materials collected will be identified only by a code number (study ID) and will be stripped of personal identifiers. The key to the code numbers will be accessible only to the research team at each clinical site; the DCC will not have access to the key.

c. Potential Risks

Safety of human participants is a major concern in a trial involving children. DXA scans involve lying on a flat table below an X-ray source while X-rays are passed through the body, allowing us to measure body composition. A potential risk of receiving DXA scans is that participants will be exposed to a minute amount of radiation. However, the amount of radiation exposure during a DXA

scan (0.015 mGy) is minimal and well within the NIH guidelines for permissible levels of radiation that may be administered to pediatric research participants. The radiation exposure from a DXA scan is much less than what a child would receive during a standard chest X-ray. The assessment process may also carry potential risks. For example, some of the questions may be upsetting to participants, and some participants might feel uncomfortable having their height and weight measured. Other risks associated with participation in the intervention include possibly feeling hungry when dieting or sore after exercising. In addition, in select children, excessive attention paid to dieting may lead to an eating disorder or to growth problems. There are also several potential risks to family members in the course of treatment. First, there is a degree of inconvenience for family members who may miss work, school activities, meetings, etc. Second, there is the risk, as there is in any treatment, of a stress reaction occurring. Third, there may be some family disagreements during the implementation of the intervention as issues of family functioning, communication, and discipline may be discussed. Finally, there is the risk of a breach of confidentiality of a family member.

2. Adequacy of Protection Against Risks

a. Recruitment and Informed Consent

Participants will be recruited from the St. Louis and Seattle metropolitan areas. Participants will be recruited through local media outlets (television, newspaper, Internet, and radio), schools and organizations, physician referrals from pediatrician offices, and clinics treating weight problems and obesity. Additional resources are available at each site to facilitate recruitment during the proposed study. At Washington University School of Medicine (WUSM), Dr. Wilfley directs the Weight Management and Eating Disorders Program (WMEDP). Dr. Wilfley has an established history of successfully using the Washington University Pediatric and Adolescent Ambulatory Research Consortium (WUPAARC), an established practice-based research network of 68 community pediatricians affiliated with WUSM with over 100,000 children and adolescents in their practices, as well as an established collaboration with the Adolescent Center at St. Louis Children's Hospital. Additional study recruitment support is available through the Volunteers for Health (VFH) website. At Seattle Children's Hospital, Dr. Saelens has the support of the director of the Center for Health Services and Behavioral Sciences, home to the Children's Obesity Action Team (COAT), which recently established a Child Wellness Clinic targeting childhood overweight.

Both Drs. Wilfley and Saelens have successfully recruited participants for previous clinical trials. In Dr. Wilfley's previous study of childhood and adult obesity, she recruited 204 families with at least one obese child and parent and screened 1,161 potential families. In addition, Dr. Wilfley has a successful track record in recruiting overweight and obese participants for treatment research in St. Louis using community-based recruitment methods. In her currently funded multi-site obesity and BED treatment study, Dr. Wilfley's site at Washington University successfully met the study goal of recruiting 105 patients in the specified timeframe, screening over 970 potential participants in the process. In all of her treatment studies, Dr. Wilfley has achieved high rates of minority participation. In Dr. Saelens' recent adolescent obesity trial, he recruited 59 overweight adolescents over 4 months through pediatricians' offices. Of these, 79% were assessed and randomized. Dr. Saelens has also successfully recruited participants for large observational studies of built environment and physical activity, with estimated recruitment rates of the general population between 20-30% of eligible individuals.

With both Dr. Wilfley's and Dr. Saelens' established records of successfully recruiting participants for clinical trials, and with an estimated 32,000 overweight children ages 7-11 in the St. Louis and Seattle areas combined[59] (calculated from the 16.5% prevalence of overweight children across the United States),[60] we expect that there will be no difficulty in recruiting 172 families [172 parents and their 172 children] in separate cohorts (2 at each site).

Given that prevalence rates for overweight are similar for male and female youth (18.2% and 16.0%, respectively),[61] we expect to recruit equal numbers of **male and female children**. In addition,

as obesity is a significant problem among racially and **ethnically diverse populations,**[8,62] aggressive efforts will be made to obtain an ethnically representative sample of the St. Louis and Seattle metropolitan area populations. While the St. Louis and Seattle areas have similar proportions of Caucasian/White populations, the non-White populations differ, with African-Americans making up the second largest race population in St. Louis and Asian/Pacific Islanders constituting the second largest race population in the Seattle area. Among these three races/ethnicities, the prevalence of overweight/at-risk-for-overweight in elementary school-aged children is generally highest among African-American populations; however, childhood overweight/at-risk-for-overweight prevalence rates among the Caucasian/White and Asian/Pacific Islander populations are significant as well, with rates around 15-20%.[61,63,64] We thus anticipate that relatively more African-American participants will be recruited in the St. Louis area, and relatively more Asian/Pacific Islanders will be recruited in the Seattle area.

Each site has developed a minority recruitment plan that specifically addresses the demographics of the respective community:

St. Louis: The ethnic breakdown of the St. Louis recruitment area is 75% Caucasian, 22% African-American, and less than 3% Asian, Hispanic, Native American and Pacific Islander combined. In the past, Dr. Wilfley's lab has been successful with minority recruitment using a **community outreach approach**, forming liaisons with leaders of community-based multi-cultural organizations (e.g., African-American neighborhood associations) and placing advertisements in local publications with a large minority subscribership (e.g., *St. Louis Chinese American News, Hispanic St. Louis, St. Louis American*). The multi-cultural organizations are headed by community leaders who have a familiarity with and passion for the wellbeing of their community. They work to bridge the gap of language, knowledge, and values between cultures by familiarizing their communities with our available services through word-of-mouth referrals, community assessment, and education. In addition, our liaisons will be encouraged to provide study information and materials (e.g., study brochures) to community practices and clinics, and to offer recommendations for media outlets targeted specifically to these populations. Liaisons with ethnically diverse communities also exist through a number of institutions affiliated with WUSM; for example, WUPAARC, and numerous other facilities of WUSM in support of the proposed study, have access to minority populations and have committed to publicizing the study and providing referrals.

Seattle: The ethnic breakdown of the greater Seattle metropolitan area (King County, WA), based on the 2005 American Community Survey update of the U.S. Census population estimates of race, is 73.1% Caucasian, 13.3% Asian, 5.7% African American, and about 7.9% other races and individuals of multiple races. Recruiting youth from a child wellness clinic, pediatrician offices, and mass mailings throughout the greater Seattle area increases the likelihood of obtaining samples that are representative of the ethnic and racial diversity of the region. Advertisements will be placed in the *Seattle Times* and newspapers specific to minority populations (e.g., *Federal Way Mirror, Northwest Asian Weekly*). The large distribution of the *Seattle Times* is of benefit to placing ads for recruitment because it reaches a diverse population. Participants will be recruited through an obesity treatment clinic at Children's Hospital and Regional Medical Center (CHRMC), community pediatricians' offices, and mass mailings sent to families living in the greater Seattle area. The Child Wellness Clinic is a new CHRMC clinic targeting childhood overweight, stemming from the work of the Children's Obesity Action Team (COAT). COAT is a multidisciplinary group of clinicians and investigators from CHRMC interested in advocacy, treatment, and development of resources for overweight children and teens, families and the providers who work with them. The National Initiative for Children's Healthcare Quality (NICHQ) recently ranked COAT as one of the top six in 100 submissions for the 2006 National Recognition Awards for Health Care Programs Addressing Childhood Obesity. During community pediatrician office visits, the research study will be described to practices and

materials/flyers left for distribution to interested families. For the mass mailings, households with children in the greater Seattle area will be identified through a consumer marketing company that uses public information to identify individuals/households. Dr. Saelens has used this recruitment strategy successfully for both treatment and behavioral epidemiologic studies among children (approximately 30% non-White study enrollment).

To further facilitate ethnic minority inclusion, treatment will be conducted to **minimize logistical obstacles** that would prevent eligible participants from taking part. For example, we will schedule treatment sessions at various times, including evening hours, so as to not discourage working individuals from participating. In addition, treatment will be delivered in a culturally sensitive manner, and adaptations will be made to accommodate low-literacy individuals, including providing audiotapes or written materials and replacing words with pictures where applicable. The proposed study's inherent focus on the family, rather than on the individual as the unit of treatment, is assumed to be strongly acceptable for collectivistic, ethnically diverse populations. Also, the content of the sessions themselves will reflect sensitivity to cultural diversity in individuals. For example, within family-based sessions, discussions of food or parenting skills will take into account the appropriate cultural manifestations of these behaviors. The study follows a similar model of the one used in the "Treatment Options for Type 2 Diabetes in Adolescents and Youth" TODAY study, of which we are a part. The TODAY study utilizes a family-based lifestyle intervention for weight loss in youth with type 2 diabetes and has successfully recruited, thus far, a largely low or middle income, primarily racial/ethnic minority population.

Participants will meet with the PI or a trained staff member and will be given written and verbal information about the study. Full disclosure of the purpose of the study, the benefits and risks to individuals who participate, and the confidential nature of information obtained during the study will be explained to participants. Families will be aware from the outset that there are two phases of the study, four months of weight loss and eight months of maintenance; they will also be aware that they will be randomly assigned to a maintenance condition and that they will not be informed of the maintenance condition to which they have been assigned until the end of the weight loss phase of treatment. The staff member will answer any questions the family has about the study, and then participants will be consented according to the policies and procedures of the WUSM and Seattle Institutional Review Boards (IRB). The child will have a separate assent form. The participants will agree to participate in both phases of the study. A copy of the signed consent/assent forms and study staff contact information will be given to the potential participants, and the original consent/assent forms will be kept in the participant's confidential research record. These consent/ assent forms will include the participant's consent for audiotape recording of sessions for evaluation, treatment, research, and training related to the study; however, participants will not be excluded from the study if they refuse audiotaping. In our experience, less than 1% of participants refuse audiotaping.

b. Protections Against Risk

All key personnel involved in the design or conduct of research involving the human subjects will receive the required education on the protection of human research participants prior to the start of the study.

Each child will be cleared for entry into the study based on a complete physical examination by his or her primary care provider. Participating parents will be given a clearance form to be used by their primary care provider to provide written documentation of their ability to participate in the study. Our assessment team will maintain information on low cost health care clinics and local treatment providers, and, if a parent does not have a primary care provider, a referral can be made. Consultation from a physician will be obtained, upon written release from the patient, if at any point during the study a participant requires medical attention.

Staff members administering assessments will be made aware of the possibility of a participant feeling discomfort about answering questions or having his/her height and weight measured.

Participants will be informed that they do not have to answer any questions that make them uncomfortable, and height and weight will be measured in private to minimize embarrassment. The total time required for a DXA scan is 15 to 20 minutes. At all times, participants will be able to speak with the technologist operating the machine and their parents, who will be permitted to stay in the room. The children and their parents will be informed that they may ask to stop the scan at any time. Additionally, since the children will be asked to remove articles of clothing or jewelry containing metal, they will be allowed to undress privately and will be given a hospital gown to wear. To avoid any potential discomfort, both children and their parents will be reminded to wear clothing without metal (e.g., buttons, zippers). Participants will be advised of the possibility of hunger with dieting or soreness after exercise. In order to reduce the risk of exercise-related injury, all participants will be encouraged to meet with and follow the primary care provider's instructions regarding exercise. On an ongoing basis, the family meetings will serve as the primary venue to detect and address any eating disturbance, and therapists will be trained to monitor, recognize, and intervene if symptoms of eating disordered attitudes or behaviors emerge. To the extent possible, flexibility in scheduling treatment sessions and assessments will help minimize the inconvenience of missing work, school activities, or meetings due to treatment obligations. Having expert and well-supervised therapists conduct treatments will mitigate the risk of a stress reaction to treatment occurring. The therapists will be aware of such stress responses in their early form, and conduct treatment in such a way as to reduce such responses. Therapists will also be trained to deal with potential family disagreements. Participants who are observed to be consuming nutritionally inappropriate intakes, with regard to either the quantity or quality of foods consumed, will receive individualized counseling to assist them in achieving appropriate intake. Should a participant become symptomatic during treatment, the family therapist will assess the problem, and in consultation with the center PI, decide whether to withdraw the individual from treatment and/or refer them for treatment elsewhere. This will be stated in the consent form. Participants will be informed of alternative treatments, including joining an organized youth physical activity program or youth sports team at the YMCA or other organization, talking with one's family physician or pediatrician about how to help one's child lose weight, taking part in other commercially available child fitness or weight loss programs or meeting with a pediatric dietician or fitness trainer, and if so desired, referrals will be made. Potential participants will also be informed that they may drop out at any time during the study.

Confidentiality: Patient confidentiality will be maintained in compliance with HIPAA regulations. Any identifying information will be kept anonymous, and patient records will be kept in locked files accessible only by those directly involved with the implementation of the study. All materials, discussions, and proceedings of the Data Safety and Monitoring Board (DSMB) are completely confidential, and members and other participants in DSMB meetings are expected to maintain confidentiality. All employees of Washington University with access to protected health information have been required to complete HIPAA training and to be aware of and comply with the Privacy Regulations and the Washington University Privacy Policies and Privacy Procedures, effective April 14, 2003. All employees of Seattle Children's Hospital with access to protected health information are also required to complete HIPAA training and comply with the Seattle Children's Hospital Privacy Procedures.

If any participant appears to be in crisis, appropriate action will be taken based on established suicide and crisis assessment protocol, and any adverse event reported promptly to NIMH and to the IRBs at Seattle's Children's Hospital and Washington University School of Medicine.

Adverse Events: For the purpose of this study, adverse events will be defined as unanticipated problems involving risks to the study participant. A serious adverse event will be defined as any untoward occurrence that results in death, is life threatening, or creates persistent and significant disability. The initial reporting of adverse events of any kind will take place with the study staff consulting with the respective PI at each site, Dr. Wilfley (WUSM) or Dr. Saelens (Seattle), who will decide if the event is of such a severity that it requires discontinuation of treatment, and whether the

participant should remain in the study or be withdrawn and referred elsewhere. All serious adverse events will be immediately reported to the WUSM and Seattle IRB. All adverse events, with a detailed explanation of the event, will be forwarded to the appropriate Human Subjects Committee (WUSM or Seattle) and the DSMB. In addition, at its regular meeting the DSMB will summarize all adverse events of any severity, to be forwarded to the WUSM or Seattle IRB via the PI. For details of the Data Safety and Monitoring Plan (DSMP), see below. It is important to note that in Dr. Wilfley's previously completed trial, the procedures mentioned above were used to protect against and minimize potential risks to participants. These procedures also proved effective in preventing physical complaints and adverse events.

3. Potential Benefits of the Proposed Research to Human Subjects and Others

The prevalence of overweight in both children and adults has been increasing at an alarming rate. Effective treatments for childhood obesity have the potential to provide substantial health benefits and to decrease the number of children tracking obesity into adulthood. Although we do not guarantee any benefits from this study, the intervention, if successful and if it replicates our previously completed study, has several potential benefits. Benefits to participants include improved physical health, improvements in the quality of nutritional intake, increases in physical activity, and long-term reduction in body weight through participation in behavioral weight loss. The treatment may also reduce the stress on the family posed by the burden of obesity. In addition, it is possible that skills to solve ongoing problems that perpetuate obesity may improve. The growing prevalence of obesity and the health-related consequences highlight the need to examine potential treatments that may help children to lose weight and sustain weight loss over time. Therefore, the potential risks that are associated with this study, such as minimal exposure to radiation from the DXA scans, feelings of discomfort while answering questions or having height and weight taken, a small chance of developing an eating disorder, and possible occurrences of family disagreements during treatment, are reasonable when considering the many health related benefits that the participants and their families may gain.

4. Importance of the Knowledge to be Gained

As stated above, identifying effective maintenance interventions in reducing overweight in children, and in turn, preventing obesity in adults, is of the utmost importance. We expect the results of this study to contribute to our understanding of maintenance treatments for overweight children. Increasing our knowledge in this area has implications for both the medical and health-related fields such that reducing obesity will also aid in decreasing associated health risk factors such as coronary heart disease, hypertension, cardiovascular disease, and diabetes. Benefits to future patients, researchers, clinicians, and health care planners could also include the development of treatment procedures for the control of overweight in children who are at high risk of becoming obese adults.

5. Data and Safety Monitoring Plan (DSMP)

Data Safety and Monitoring Board (DSMB)

An independent panel of experts, consisting of at least three members who are not affiliated with the study – including two clinicians with expertise in pediatric obesity and a patient advocate – will be appointed to constitute a Data Safety and Monitoring Board (DSMB). Members will be named prior to the commencement of the study. In addition, the study PI (Dr. Wilfley), director of the DCC (Dr. Schechtman), and designated staff will attend the DSMB meeting (as non-voting participants) and will be responsible for preparing and presenting data reports from the study. The DSMB will provide oversight and ongoing monitoring of participant safety, quality of data collection, and integrity of the study. The study data will be reviewed by the DSMB every six to twelve months via teleconference. The DSMB will receive a report before each review date. These reports will include the major variables necessary for monitoring safety and quality of data collection and integrity of the study, and

will include otherwise blinded outcome data. Because study protocol and consent forms are relevant to the safety and quality of data, the DSMB will also review these documents before the onset of the study. Based on this review, the DSMB will possess the authority to prevent the study from starting or to stop the study after it has started.

Overview of DSMB Role:

- Initially, review the study protocol with regard to recruitment, randomization, intervention, subject safety, data management, quality control, and analysis plans, and identify needed modifications. The DSMB will then identify the relevant data parameters and the format of the information to be regularly reported.
- Review data (including masked data) over the course of the trial relating to efficacy, recruitment, randomization, adherence, retention, operating procedures, forms completion, intervention effects, ethnic/racial minority inclusion, and subject safety.
- Identify problems relating to safety over the course of the study. Inform Study PI, Project Manager, and Project Coordinator by phone and via written report of their findings and recommendations.
- Identify needs for additional data relevant to safety issues and request these data from the study investigators.
- Propose appropriate analyses and periodically review data on safety and outcomes.
- Make recommendations regarding recruitment, treatment effects, adherence, retention, safety issues, and continuation of the study.

The frequency of data review and type of data is summarized in the following table:

Data	**Review Frequency**
Participant accrual (with demographic data)	Semiannually
Adverse events	Within 72 hours
Adverse and other events review	Semiannually
Intervention compliance	Semiannually
Discontinuation rules report regarding statistical power implications of drop outs and missing data	Yearly

Data Safety

All data collected for this study, as well as all study-related patient files, will be kept in locked cabinets in study staff's offices at each site. No data, files, or any other study participant information will leave these offices. Only the PI, research staff, and study therapists will have access to these files and only with reason for access. Treatment session audio tapes will be stored at each center, labeled by study ID, date and session number, without further identifiers. These tapes will be stored on the secure Washington University server with restricted access and will be erased some three years after the end of the study, depending on the policy set by the Study Executive Committee. A copy of selected sessions, labeled as above, will be sent for auditing. These copies will be erased immediately following auditing.

No identifying data will be sent to either center, and all data entered into the computer will be by participant number (study ID). When conversations take place between the DCC and clinical site personnel, only participant numbers (study IDs) will be used. No list of names linked to participant numbers will be kept at the DCC.

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